



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/937,320 | 03/05/2002 | Andre Rougier | 016800-464 | 9439 |

21839 7590 06/02/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

| |
|----------|
| EXAMINER |
|----------|

YU, GINA C

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1617

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,320

Applicant(s)

ROUGIER ANDRE ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 17, 16-19, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "its analogues" in claim 13 is viewed vague and indefinite because there is insufficient antecedent basis for this limitation in the claim.

The term "vigars" in claims 16-19 appears to be a non-existing word. Did applicants mean to recite "sugar"?

The remaining claims are rejected as depending on an indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 12, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner (US 5470874).

The broadest claims, claims 12 and 13, recite the methods of increasing the level of differentiation of skin fibroblasts and keratinocytes, respectively, by topically applying vitamin C or its analogues to an individual in need thereof.

Lerner discloses method of treating skin by topically applying vitamin C (ascorbic acid). See col. 2, lines 24 – 46. The reference teaches that vitamin C is “essential for collagen synthesis and wound healing”.

Lerner is silent about “increasing the level of differentiation of skin fibroblasts” in Claim 12 and “stimulating the synthesis of cutaneous vimentin” in Claim 14 and keratin 10 in Claim 15.

The claiming of a new use, new function of unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See In re Best, 562 F.2d 1252, 1254, 195 U.S.P.Q. 430 433 (C.C.P.A. 1977). When the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated. See In re May, 574 F. 2d 1082, 1090, 197 U.S.P.Q. 601, 607 (C.C.P.A. 1978).

In this case, the Lerner method of topically applying ascorbic acid to skin for collagen synthesis and wound healing meets the limitation of the instant claims because it is viewed that applicants merely found the mechanism of collagen synthesis or new property of ascorbic acid. For example, it is well known in the art that stimulation of fibroblasts proliferation produces keratinocytes growth factors (such as keratin 10) and stimulates collagen synthesis. See Schinitzky et al. (WO 91/18614), p. 3, lines 7-21. In this case the claimed methods are merely directed to result or property of ascorbic acid and thus anticipated by the Lerner reference.

2. Claims 13, 17, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Perricone (US 5574063).

Perricone discloses a method for treating skin disorders of collagen deficiency by topically applying fatty acid ester of ascorbic acid, particularly ascorbyl palmitate. See abstract.

The reference is silent about "differentiation of skin keratinocytes" in Claim 13.

As discussed above, it is well settled in patent law that the claiming of a new use, new function of unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See In re Best, at 1092. A claim is anticipated when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. See In re May, .

In this case, Perricone anticipates the instant claim because it is viewed that applicants merely found the mechanism of collagen synthesis. Schinitzky teaches that it is well known in the art that stimulation of fibroblasts proliferation produces keratinocytes growth factors (such as keratin 10) and stimulates collagen synthesis. See Schinitzky, Id. In this case, the claimed method is merely directed to result or property of ascorbic acid or its analogues and thus anticipated by the Perricone reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner as applied to Claims 12, 14, and 15 as above, and further in view of Perricone.

While Lerner fails to teach the derivatives recited in the dependent claims, It is well settled in patent law that a prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities.

Perricone teaches that fat-soluble fatty acid esters of ascorbic acid treats skin disorders caused by collagen deficiency. The reference teaches that vitamin C esters can be delivered into skin tissues without losing efficacy, employed without adverse side effects, and is particularly advantageous because it is stable against oxidation when exposed to air. Furthermore, the reference teaches to use vitamin C esters with vitamin E, a fat-soluble vitamin, to obtain synergistic results. See 2, line 30 – col. 3, line 2. Cosmetically acceptable forms such as lotion, cream, ointment, and soap can be used. See col. 3, lines 3- 14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Lerner by substituting vitamin C with the fatty acid esters of ascorbic acid such as ascorbyl palmitate, as motivated by Perricone, because of the expectation of successfully producing 1) a topical composition for similar utilities, i.e., collagen synthesis, and 2) more stable composition and efficient delivery of the vitamin C. The skilled artisan would have been also motivated to use the fatty acid ester form of ascorbic acid to combine with vitamin E to obtain synergistic activity of vitamin C.

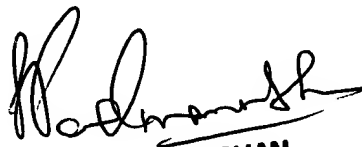
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Gina Yu
Patent Examiner


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER